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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,787	07/28/2003	Slobodan Dan Dimitrijevic	0684CG.034678/DIV	5209

34725 7590 06/29/2006

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EXAMINER

GHALI, ISIS A D

ART UNIT PAPER NUMBER

1615

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/628,787	Applicant(s) DIMITRIJEVICH, SLOBODAN DAN	
	Examiner Isis Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 25 and 27-40 is/are pending in the application.
4a) Of the above claim(s) 25 and 27-40 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-9 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>01/10/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicants' IDS filed 01/10/2006, and amendment filed 04/17/2006.

Claims 1-9, 25, 27-34 were previously presented.

Claims 35-40 are currently added.

1. Newly submitted claims 35-40 are directed to two new inventions that are independent and distinct from the invention originally prosecuted, claims 1-9, for the following reasons:

(a) Claims 1-9 directed to patch that requires acid treated collagenous material and specifically requires collagen type I.

(b) Claims 35-39 are directed to patch that is distinct from the patch of claims 1-9 for the following reasons:

first, the patch of claims 35-39 require one collagenous material selected from: collagen type I, interstitial collagen, collagen type III, V, or IX, therefore, claims 35-39 do not require collagen type I;

secondly, claims 35-39 do not require acid treated collagenous material.

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(c) Claim 40 is directed to method of making anti-adhesion patch that is distinct from the patch of claims 1-9 and claims 35-39 for the following reasons:

first, the method of claim 40 does not require any specific collagenous materials such as specific types of collagen, or any specific cells as required by claims 1-9 and 35-39;

secondly, the method of claim 40 does not require acid treatment as required by claims 1-9; and

thirdly, the patches of claims 1 and 35 not necessary produced by the method of claim 40 that requires matrix organization medium to form mono-cellular tissue equivalent, and can be produced by different method such as the method described in example 5 of US 5,223,420 including steps of mixing, vigorously stirring, molding, filtering and drying.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 35-40 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. This application contains claims 25, 27-34 drawn to an invention nonelected with traverse in response filed 02/10/2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 25, 27-40 are withdrawn from further consideration.

Claims 1-9 are included in the prosecution.

The following rejections have been overcome by virtue of applicant's amendment:

- (a) The rejection of claims 1-8 under 35 U.S.C. 102(b) as being anticipated by US 5,223,420 ('420), because the reference does not teach acid treated collagen.
- (b) The rejection of claims 1, 4-9 under 35 U.S.C. 102(b) as being anticipated by US 5,842,477 ('477), because the reference does not teach acid treated collagen.
- (c) The rejection of claims 1-8 under 35 U.S.C. 102(e) as being anticipated by US 2002/0015724 ('724), because the reference does not teach acid treated collagen.
- (d) The rejection of claims 1, 4-8 under 35 U.S.C. 102(e) as being anticipated by US 2002/0028243 ('243) because the reference does not teach acid treated collagen.
- (d) The rejection of claims 1-9 under 35 U.S.C. 103(a) as being unpatentable over US 6,451,032 ('032) in view of US 6,077,987 ('987), because the combination of the references does not teach acid treated collagen.
- (e) The rejection of claim 2 and 3 under 35 U.S.C. 103(a) as being unpatentable over US '477 in view of US '032, because the combination of the references does not teach acid treated collagen.

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(f) The rejection of claims 2 and 3 under 35 U.S.C. 103(a) as being unpatentable over US '243 in view of US '032, because the combination of the references does not teach acid treated collagen.

(g) The rejection of claim 9 under 35 U.S.C. 103(a) as being unpatentable over any of US '420, US '724 or US '243 each in view of US '987, because the combination of the references does not teach acid treated collagen.

The following rejections have been discussed in the previous office action, and are maintained for reasons of record:

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,596,304 ('304).

US '304 discloses collagen-based material to prevent post surgical adhesion comprising mixture of collagen I and III, and fibroblasts (abstract; col.4, lines 23-26; col.6, lines 3-7; col.8, lines 64-65; col.9, lines 18, 23-27; col.10, lines 6-7). The collagen

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used is acid treated and processed, therefore, it is inherently a cellular collagen (col.4, lines 27-29).

Response to Arguments

5. Applicant's arguments filed 04/17/2006 have been fully considered but they are not persuasive. Applicants traverse this anticipatory rejection by arguing that the reference does not include each and every element of the invention as claimed. It is not sufficient to merely find one component of the claimed invention to present a proper 35 U.S.C. 102 rejection. US '304 disclosed heat denaturated collagen at 40⁰ C -50⁰ C, i.e. not in the same natural state and eliminating the three-dimensional structure of collagen. Applicants argue that the collagen disclosed by the reference is not a cellular collagen.

In response to these arguments, applicants' attention is drawn to the scope of the present claims which is patch comprising acid treated a cellular collagen and component from cells. US '304 disclosed patch comprising acid treated collagen that also processed, i.e. a cellular collagen, and fibroblasts. US '304 disclosed collagen type I as preferred and used in example 1, and disclosed acidic collagen in example 2. The reference further disclosed combination of collagen type I and III. Additionally, the reference disclosed the patch to be used for the same purpose as intended by applicants' patch, i.e. prevent post surgical adhesion (abstract; col.2, lines 56-57). Therefore, the reference disclosed each and every element of the claimed invention. In response to applicant's argument that the reference disclosed heat denaturated

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collagen at 40⁰ C -50⁰ C eliminating the three-dimensional structure of, applicants' attention is drawn to the claims' language that does not exclude heat denaturation, and the claims do not require three-dimensional structure. US '304 anticipates the claimed anti-adhesion patch comprising acid treated acellular collagen and cells.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '304 in view of US 6,077,987 ('987).

US '304 teaches collagen-based material to prevent post surgical adhesion comprising mixture of collagen I and III, and fibroblasts (abstract; col.4, lines 23-26; col.6, lines 3-7; col.8, lines 64-65; col.9, lines 18, 23-27; col.10, lines 6-7). The collagen used is acid treated and processed, i.e. cellular (col.4, lines 27-28).

However, US '304 does not teach the fibroblast cells to be engineered cells as claimed in claim 9.

US '987 teaches method for enhancing the efficacy of tissue repair and promoting wound healing using engineered cells in a protein matrix (abstract; col.4, lines 5-13). The engineered cells are fibroblast from epidermal cells (col.4, lines 35-38, 45-50).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide film comprising acid treated collagen and fibroblast to prevent post surgical adhesion as disclosed by US '304, and replace fibroblast by engineered dermal fibroblast as disclosed by US '987, motivated by the teaching of US '987 that the engineered cells enhance the efficacy of tissue repair and promote wound healing, with reasonable expectation of having film comprising acid treated collagen and engineered fibroblast that promote wound healing without adhesion between the healing wound the adjacent tissues, as desired by applicants.

Response to Arguments

9. Applicant's arguments filed 04/17/2006 have been fully considered but they are not persuasive. Applicant traverse this obviousness rejection by arguing that:

- Applicants refer to the previous arguments regarding US '304.

In response, the examiner position addressed on section 5 of this office action is hereby repeated.

- Applicants argue that the rejection is based solely on the assembly of art based on the present invention.

In response to this argument, the rejection is totally based on the disclosure of the prior art that were available at the time of the invention because US '304 clearly disclosed anti-adhesion patch comprising acid treated collagen and fibroblast cells, however, the reference does not teach the cells to be engineered cells as instantly claimed in claim 9. Therefore, the examiner relied upon US '987 that teaches engineered cells used to enhance tissue repair. In any event, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

- Applicants argue that US '987 is directed to the use of cells, and the present invention is acellular.

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In response to this argument, applicant's attention is drawn to the scope of the claims that recite only the collagen is acellular, and not the whole patch is a cellular because the claims recite two components: 1) is acellular collagenous material, and 2) cellular component. Therefore, US '987 is reasonably pertinent to the particular problem with which the applicant was concerned which is incorporated cells into the collagen.

- Applicants argue that there is not a single, teaching, suggestion or motivation taught in the art cited to combine the references. Applicants request that the exact cites to the language that is used to connect the references be provided.

In response to this argument, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one having ordinary skill in the art at the time of the invention, having available in between hands both US '304, teaching anti-adhesion patch comprising acid treated collagen and cells, and US '987, teaching engineered cells enhance tissue repair, would have been motivated to replace the cells disclosed by US '304 by the engineered cells disclosed by US '987, motivated by the teaching of US '987 that the engineered cells enhance the efficacy of tissue repair and promote wound healing, with reasonable

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expectation of having patch comprising acid treated collagen and engineered cells that promotes wound healing without adhesion, as desired by applicants.

The examiner is pointing out to the exact cites to the language that is used to connect the references: US '304 col.8, line 64 disclosed the fibroblasts, and US '987 in the first three lines of the abstract; col.4, lines 5-12, 49-50, teaches engineered fibroblasts to enhance tissue repair.

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by claim 9 would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

Isis Ghali